

U.S. Department of Justice
Drug Enforcement Administration

REPORT OF INVESTIGATION

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1. Program Code	2. Cross File Related Files	3. File No. [REDACTED]	4. G-DEP Identifier
5. By: James W Graumlich, DI At: Orlando DO	<input checked="" type="checkbox"/> [REDACTED] <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	6. File Title PUBLIX ORLANDO PHARMACY WHSE.	
7. <input checked="" type="checkbox"/> Closed <input type="checkbox"/> Requested Action Completed <input type="checkbox"/> Action Requested By:		8. Date Prepared 09-29-2011	
9. Other Officers: DI Linda Stocum; DI Deborah George			
10. Report Re: Case Closing; Scheduled In-Depth [REDACTED]			

A. SYNOPSIS:

This investigation was initiated pursuant to the FY-2011 Investigative Workplan, Orlando District Office, Diversion Control Group. PUBLIX ORLANDO PHARMACY WAREHOUSE, 1950 Sand Lake Road, Bldg. 3, Orlando, Florida 32809 is registered with the DEA as a distributor in schedules III, IIIN, IV and V, DEA number RP0331924, expiration 03/31/12.

The on-site investigation took place from 08-01-2011 to 09-29-2011. The Diversion Investigators audited the following drugs and found no discrepancies: Hydrocodone/Acet. 5/500mg; Hydrocodone/Acet. 7.5/750mg; Alprazolam .25mg; Diazepam 10mg; Cheratussin-pint bottles and Promethazine with Codeine-pint bottles. It should be noted there was initially a discrepancy with the audit due to the fact that the firm does "line item" receiving on its purchase orders, accurately documenting the date received, but the computer system assigns the same date received for all orders in the computer system, using the date the last item is received and the purchase order is close out. This was not a violation due to the fact that the firm's computer records are considered secondary records and the primary record (the actual purchase order) does indicate the physical date received.

The firm does not have operations hours for the Pharmacy Department on Fridays. No further action is anticipated, this case is closed.

11. Distribution: Division District [REDACTED] Other	12. Signature (Agent) James W Graumlich, DI	13. Date 09-30-2011
	14. Approved (Name and Title) /s/ Susan Slyker, GS	15. Date 09-30-2011

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B. ENCLOSURES:

1. Notice of Inspection
2. Computation Chart
3. Purchase Order Package
4. Sales Invoice
5. Alarm Contract Rider

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C. Basis for Investigation

This in-depth investigation was initiated pursuant to the Orlando District Office Diversion Workplan for FY-2011. PUBLIX ORLANDO PHARMACY WAREHOUSE, 1950 Sand Lake Road, Bldg. 3, Orlando, Florida 32809, is registered with the DEA as a distributor in schedules III, IIIN, IV and V, DEA number RP0331924, expiration 03-31-2012.

D. Subject Firm's Background

1. General: PUBLIX ORLANDO PHARMACY WAREHOUSE, hereafter referred to as PUBLIX, is a wholesale distributor of food, dry goods, health and beauty products and controlled substances located at 1950 Sand Lake Road, Bldg. 3, Orlando, Florida 32809. The firm has occupied its current location for 15 years but has only been registered to handle controlled substances since 2005. PUBLIX Supermarkets, Inc. is an employee-owned retail grocery supermarket chain. PUBLIX employs more than 132,000 associates and operates 1036 supermarkets in five states. This warehouse distributes exclusively to its 858 pharmacies in Florida, Alabama, Tennessee, Georgia and South Carolina. PUBLIX was incorporated in the State of Florida in 1927 with corporation #112252. The main branch headquarters office is located at the George Jenkins Building, P.O. Box 32024, Lakeland, Florida 33802. The Orlando warehouse is PUBLIX' only controlled substance distribution center in the United States. The company's sales area is broken down into four retail divisions: Miami, Jacksonville, Lakeland and Atlanta. Each division is led by a Division Vice President. The firm is governed by the following Board of Directors:

Name**Title****DOB**

Carol Jenkins Barnett	Chairman	[REDACTED]
William E. Crenshaw	Officer	
Hoyt R. Barnett	Vice Chair	
Charles H. Jenkins Jr.	CEO	
E. Vane McClurg	Member	
Jane Finley	Member	

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Sherrill Hudson	Member	[REDACTED]
Maria A. Sastre	Member	
Howard M. Jenkins	Member	

Principal warehouse management is as follows:

<u>Name</u>	<u>Title</u>
Bill Pelham	Distribution Mgr.
Jason BAMBERGER	Pharmacy Department Manager
Mark Shaia	Department Manager

A check in NADDIS revealed no derogatory information. Mr. Crenshaw [REDACTED], Mr. Jenkins [REDACTED], Mr. BAMBERGER [REDACTED] and Mr. Shaia [REDACTED] were indexed as Publix executives.

The PUBLIX drug warehouse employs 41 full time employees. The business hours are 5:30am to 4:00pm, Monday through Thursday. The firm has no operations hours for the Pharmacy Department on Friday. Controlled substances account for approximately 7% of the Pharmacy Department's volume. The firm also employs 136 employees at a grocery distribution warehouse on this site. The grocery distribution center deals with PUBLIX grocery stores only.

2. Registrations and Licenses:

The firm holds the following licenses/registrations:

- State of Florida, Department of Health, Division of Medical Quality Assurance, License #22:01471, expiration 09-30-2011.
- State of Georgia, Wholesaler Pharmacy, Permit #PHWH002174, expiration 06-30-2013.
- State of Alabama, State Board of Pharmacy, Manufacturer/Wholesaler/Distributor Permit #193258, expiration 12-31-2012.

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- State of Tennessee, Board of Pharmacy; Non-Resident Wholesaler/Distributor/Manufacturer, ID #0000002343, expiration 06-30-2011.
- South Carolina Department of Labor, Licensing and Regulation, Board of Pharmacy, Non Resident wholesale, Distributor, Manufacturers Permit #70-008528, expiration 06-30-2012.

3. History:

- [REDACTED]; Approval of Application, Distributor in schedules III, IIIN, IV, and V dated 12/05/05.
- [REDACTED]; Scheduled In-Depth, No violations.

E. Persons Interviewed and Individual Responsibility:

On 08-01-2011 Diversion Investigators (DIs) James Graumlich and Linda Stocum initiated an on-site inspection at the PUBLIX Distribution Center, 1950 Sand Lake Road, Bldg 3, Orlando, FL 32809. After identifying himself to Mr. Pelham and Mr. Shaia, DI Graumlich presented his credentials to Jason BAMBERGER, Pharmacy Department Manager, who read his rights pursuant to 21 CFR 1316.08(b) and signed the Notice, consenting to the inspection (Enclosure 1).

F. Scope of Investigation

This on-site investigation began on 08-01-2011 and concluded on 09-29-2011. The audit period ran from Beginning of Business (BOB) 02-01-2011 to BOB: 08-01-2011. The DIs audited 6 drugs based on the firm's ARCOS reports and feedback from PUBLIX managers.

Accountability:

The audit showed no discrepancies for any of the audited drugs. A copy of the Computation Chart is included as Enclosure 2. There were initially discrepancies with several of the drugs showing overages or shortages, but

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these discrepancies were resolved after talking through the firm's receiving procedures and discovering the firm does what it calls "line item" receiving. This means that the firm receives individual items from a purchase order on different days. However, the purchase order is not "closed" in the firm's computer system until the last item is received. As far as the computer system is concerned, the receipt date for each item on the purchase order is listed as the date the purchase order is closed and not the physical date received. This issue was discussed with firm management and it was explained how this affected the accountability audit when these printouts were used, but the DIs could not require the firm to change this procedure as this printout was not the firm's primary record for the receipt of controlled substances.

The firm's primary record consists of the paper copy of the purchase order with packing slips and other shipping information attached. The firm's primary receiving document for each purchase order includes all the information required by DEA, showing the shipper's information, date, quantity and description of items received. The actual date an item is physically received is documented on this record.

The DIs audited the following drugs:

Schedule III:

Hydrocodone/Acet. 5/500mg-500 count bottles

Hydrocodone/Acet. 7.5/750mg-500 count bottles

Schedule IV:

Diazepam 10mg-100 count bottles

Alprazolam .25mg-100 count bottles

Schedule V:

Cheratussin-pint bottles

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Promethazine with Codeine-pint bottles

The following records were used to conduct the audit:

- 02-01-2011 cycle count
- 08-01-2011 cycle count
- Sales invoices
- Purchase orders
- Acquisition and Distribution Logs
- Credit Memos
- Computer-generated "Transaction Summary Report"
- Computer-generated "Inventory/Billing History Report"
- Freight Bills
- Tickets/picking slips for customers
- Inventory Adjustment Summary
- Active Warehouse Physical Inventory

G. RECORDKEEPING:

During the on-site inspection, DI Graumlich was informed that Jason BAMBERGER is responsible for all DEA recordkeeping and is the point of contact for reports and reporting requirements. DI Graumlich confirmed Mr. BAMBERGER was aware that records must be maintained for a period of two years in a readily retrievable manner, separate from other business records. The firm maintains computerized versions of all transaction records in its mainframe computer located at the corporate office in Lakeland, Florida. All DEA-required records were readily retrievable and maintained separately from all other business records.

1. Initial Inventory: The DIs used the firm's verified cycle count for 02-01-2011 as the Initial Inventory for their audit. Mr. BAMBERGER verified that this count was accurate.

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2. Biennial Inventory: The firm's most recent Biennial Inventory was taken on 06-30-2011. DI Graumlich verified the firm's Biennial Inventory was properly labeled and available for review.

3. Closing Inventory: DIs Graumlich and Stocum took a physical inventory of the controlled substances to be audited with the assistance of Jason BAMBERGER and Laura SLONE. The closing inventory was dated as of the Beginning of Business 08-01-2011. When sales for the day were taken into account, the physical count matched PUBLIX computer read-out of what was on hand at the beginning of business that day. Mr. BAMBERGER and Ms. SLONE attested to the accuracy and completeness of the closing count. Closing Inventory numbers used for the audit are included on the Computation Chart which is Enclosure 2

4. Receipts: The firm's primary receiving document is a purchase order which includes all the information required by DEA. The purchase order contains the name of the firm, order number, quantity, product description and the date received. The actual date an item is physically received is documented on this record. The invoice is attached to all other paperwork pertaining to the purchase of controlled substances, including PUBLIX' purchase order, the vendor's shipping list, a freight bill prepared by PUBLIX and a freight log. The original purchase records for Schedules III-V controlled substances are maintained in a file stored in the controlled substances cage. A copy of a purchase order package is Enclosure 3.

The firm also maintains computer-generated transaction reports in its computer database. The transaction reports show the product name; strength; size; invoice and purchase order; quantity; date the purchase order was closed; transaction date; and store identification. DIs used these computer printouts to assist in the audit, comparing purchases to the original paperwork to verify receipt dates.

5. Production Records: Nothing to report.

6. Distribution Records: The primary record for Schedule III-V distributions is the firm's computer generated invoice (pick slip) and the actual manifests, which are maintained by date and stored in the

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Information Services Department. All original hard copies go to the PUBLIX store the controlled substances are shipped to. The invoices are generated based upon computer orders transmitted to the Distribution Center from the individual pharmacies. Enclosure 4 is a sample sales invoice.

7. Records of Returned or Damaged Goods: Damaged or expired goods that are received from the supplier will be returned to the supplier and a credit memo generated or the products will be destroyed using an authorized destruction facility. The firm does not accept returns from their stores. All stores are internally equipped to handle the disposition of controlled substances in their possession. The returns documents and credit memos are filed in the quarantine cage. The firm utilizes a quarantine cage to store substances that are in a holding status pending destruction or return.

8. ARCOS: The firm submits the ARCOS report monthly in electronic format. According to ARCOS, the firm is current in its reporting. All hard copy ARCOS records and receipts are stored at the corporate office in Lakeland, FL. A certified ARCOS printout was received via e-mail from the ARCOS unit on 05-05-2011 and used for the inspection. The firm is current in its reporting.

9. QUOTAS: Nothing to report.

H. Drug and Equipment Security

1. Structure and Location: PUBLIX is located in an industrial park area on the South side of Orlando, FL. The Pharmacy Warehouse is building number 3 and is a freestanding single-story building. The building is constructed of block concrete reinforced with steel and measures approximately 29,000 square feet. The roof is constructed of 1½ inch metal standard decking, 4 ½ inch freezer insulation, and 1 inch rigid insulation decking, covered with tar and gravel. The firm used to be a boxed meat facility, built for refrigeration. The firm is located in a low crime area. In the event of an alarm, the Orange County Sheriff's Department will respond with response time estimated at 5 minutes or less. There is a small entry hatch on the roof of the pharmacy warehouse

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building with a magnetic contact switch and plastic seals on the door that are checked monthly. The hatch leads to the paper recycling area.

2. Perimeter Security: There are four main buildings on the site: grocery products, paper products, pharmacy warehouse and paper recycling, and the garage facility. The firm is surrounded by an 8 ft. galvanized chain link fence with wire on top, with access limited to a gate located beyond the guard station. Visitors are issued a pass after the appropriate member of the firm is contacted for approval. The main entrance to Building 3 faces east, and consists of a glass door set in a metal frame. There is one fire exit door constructed of metal and seven metal overhead doors located in the shipping and receiving areas. All doors are equipped with magnetic contact switches. The overhead doors are secured by sliding locks and padlocks, and additional alarm coverage utilizing a microwave sensor. The firm has exterior lighting located around the entire facility, and the parking lot has street lights as well. There is an alarm siren and strobe light on the exterior of the building. Two cameras are mounted on the outside of the warehouse pharmacy on the front east side of the building.

3. Controlled Substance Security: The firm's Schedule III-V controlled substances are stored in a cage located at the north end of the warehouse. The cage has three solid walls and one wall made of wire mesh. Two of the walls are constructed with 12 inch concrete block and one wall is constructed of 26 gauge steel skin and a 6 inch thick insulated wall panel. The front of the cage is constructed of 10 gauge steel mesh material, with approximately 2 X 1 inch openings. The horizontal steel bars are 57 inches apart and 2 ½ inches in diameter. The vertical steel square tube posts are 4 ft apart and 2 ½ inches in diameter. The vertical bars are bolted and brazed at all points to the concrete floor. The cage measures 36 ft deep, 30 ft high and 30 ft wide. The cage ceiling and cage door are constructed of the same black 10 gauge steel wire mesh. Entry to the cage requires a key and card access. When an employee is terminated all keys and access cards are collected and removed from the system.

The cage door has a magnetic contact switch. The cage extends to the building's perimeter walls on the north and west sides. The cage door, measuring 5' wide X 10' high, is constructed of #10 wire mesh and is

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located at the south end of the cage. The door is self-closing and self-locking and has a deadbolt lock. Alarm security in the cage is provided by a wide angle video camera located at the south end of the cage, as well as two 360 degree motion detectors located on the east side of the cage. There is a second sliding gate on the east side of the cage, measuring 2'8" X 8', which is protected by a contact switch. The cage is under a separate alarm zone. The cage also has one roll up door on the west wall used for palletized controlled substances. The roll up door is alarmed with a magnetic contact switch and key lock. There is a 360 degree motion detector located immediately outside the cage. Also outside the cage is a paper recycling area with a conveyor belt system and small door used for recycled card boxes. During hours of operation the conveyor door is open. The door leads to the recycling machine located in the recycling area and is 20ft off the ground. After business hours the door is sealed with a slide lock. The door is also alarmed with a magnetic contact switch and a motion detector mounted for complete door coverage. There are also three cameras mounted in the recycling area.

In addition to the schedules III-V controlled substances cage there is a quarantine cage. The quarantine cage is used for non-saleable and damaged items. The quarantine cage is constructed of #10 gauge wire mesh panels and located at the far south end of the warehouse. The cage is free standing and measures 14ft high, 24ft wide, and 25ft deep. The cage is bolted to the concrete floor and all bolts are brazed. The cage has a large sliding door next to a small man door. Both are constructed of 10 gauge steel mesh material. The sliding door is hinged and has sliders with a pad lock and contact switch. The main door is hinged with a self closing and self locking mechanism. The door also contains a magnetic contact switch and key lock. Access to the quarantine cage requires an access card and access code. The quarantine cage is a separate zone and the alarm keypad is mounted on the outside of the cage. There are two cameras that cover the entire quarantine cage area. Ms. SLONE and Mr. BAMBERGER are the only individuals with access to the quarantine cage. The cage has one motion detector located inside the cage providing complete coverage. The cage openings are 2 X 1 inches and the vertical posts are 2½ inches in diameter and mounted 57 inches apart.

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4. Alarm Security: The firm's security system was installed by ADT Security Services and is monitored by ADT Security Services INC., 14200 E. Exposition Blvd, Aurora, CO 80012. All equipment was purchased from ADT, who maintains and repairs the equipment. ADT installed a BOSCH D7412G digital alarm communicator and TELGARD TG300 cellular system. The system is rated as a UL Grade A commercial burglary system. The system has a 24 hour battery backup installed and runs a self test once every twenty four hours. The master control unit is located in the main entrance security area in the pharmacy warehouse. A copy of the rider to the firm's original alarm system contract is included as Enclosure 5. This documents the expansion of the firm's alarm system to the pharmacy warehouse. On 08-03-2011 DIs Graumlich and Stocum conducted an alarm test and checked with the central station to confirm that the alarm signals were received accurately. The zone violations, including all cage motion detectors and door switches, were confirmed with the ADT Security Company Operator. PUBLIX employs security personnel to man the security office and guard station during business hours and the guard station 24 hours a day. All alarm signals are received at the security office and the monitoring station. Security personnel monitor all security cameras during business hours. Cameras also record information and is maintained for 60 days.

It should be noted that, while the firm did not modify their security system, they did re-configure the pallet stacks in their cage, minimizing the coverage of their existing motion detectors. DI Graumlich suggested the addition of one motion detector and the move of another to cover the affected areas. Mr. BAMBERGER stated he would contact the firm's service provider and make the requested modifications. On 09-29-2011, DIs Graumlich and George conducted an on-site inspection of the firm's modifications and found them to be appropriately placed. The firm had left the motion in the corner over the cage walk door and the detector high on the wall overlooking the pallet racks. To cover the 2 aisles of the cage, the firm had placed two passive infrared motion detectors on the south wall looking down each aisle. The cage alarm system was tested and found to be functioning properly. The cage motion detectors and cage door were verified with ADT operator #37724.

5. Personnel Security: The firm currently employs 41 individuals in the Pharmacy Warehouse. All employees and customers must enter through the

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front guard station and through the main entrance. The main entrance opens into a security station. The pharmacy warehouse is building number 3. There is a camera installed in the main entrance area. The interior door is locked at all times and separates the office area from the warehouse. All employees enter through a main entrance, scanning their photo ID badges for electronic confirmation. The entrance is monitored by security personnel. Security personnel conduct periodic walkthroughs of the facility. Employee movements throughout the warehouse are monitored by security personnel via a closed circuit camera system which is digitally recorded and reviewed with 60 day recall. Visitors are met at the main building entrance area and escorted to the pharmacy warehouse (building #3), where a second visitor's badge is issued and all personal items are stored in a designated locker.

6. Access to Controlled Substances: The following individuals have access to the controlled substances cage and storage areas:

Name	Title	DOB	SSN
Jason BAMBERGER	Department Manager	[REDACTED]	[REDACTED]
Mike Lester	Distribution Mgr.	[REDACTED]	[REDACTED]
Priscella Miller	Lead Person	[REDACTED]	[REDACTED]
Ronald Burton	FlowRack Selector	[REDACTED]	[REDACTED]
Thad Dixon	Order Checker	[REDACTED]	[REDACTED]
Tisha Campos	Order Checker	[REDACTED]	[REDACTED]
Sandra Miller	Stocker	[REDACTED]	[REDACTED]
Michael Bowman	Putaway	[REDACTED]	[REDACTED]
Bradley Bennetts	Inv. Control	[REDACTED]	[REDACTED]
Jason Birchmire	Pharm. Operations	[REDACTED]	[REDACTED]
Emile Gerne	Order Checker	[REDACTED]	[REDACTED]
Paul Hines	Pharm. Operations	[REDACTED]	[REDACTED]
Omari Lawson	Pharm. Operations	[REDACTED]	[REDACTED]
Dale McCauley	Putaway	[REDACTED]	[REDACTED]
Christopher Nieboer	Pharm. Operations	[REDACTED]	[REDACTED]
Fred Ottolino	Pharm. Operations	[REDACTED]	[REDACTED]
Edwin Padilla	Order Checker	[REDACTED]	[REDACTED]
William Pelham	Replenisher	[REDACTED]	[REDACTED]
Zeljko Radmanovic	Pharm. Operations	[REDACTED]	[REDACTED]
Brian Smith	Replenisher	[REDACTED]	[REDACTED]

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A check in NADDIS revealed no derogatory information on any of the above individuals. Mr. BAMBERGER was indexed as a result of his employment with PUBLIX.

The corporate office conducts reference and background checks on all prospective employees. Additionally, new employees are subject to drug screening. All prospective employees are interviewed at the pharmacy warehouse site and the human resources department at the corporate office receives a recommendation from the warehouse staff regarding the hiring of prospective pharmacy warehouse personnel.

7. Procedural Security:

a. Controlled Substances Shipping: All PUBLIX pharmacies use the firm's closed system, proprietary software to order controlled substances from the pharmacy distribution center. The warehouse accepts or rejects the order from its stores based on trends and events. The firm generates pick slips via an interactive voice system used by warehouse personnel to fill orders. The distribution of each controlled substance is inventoried, cross checked and inspected prior to shipping. Each distribution is documented and tracked in the firm's computer system by product number. All controlled substances orders are pulled and checked by at least 3 individuals before being placed in totes and transferred to the shipping dock. The individuals are identified as a Selector, Order Checker and Dock Coordinator. All three individuals must verify the count before items are shipped.

Order pickers wear a wireless headset that is connected to a voice system. Once the picker receives the order, the computer generates a screen line for the same invoice. The picker logs on and begins picking. Once each item is picked it must be scanned by the picker and placed into a tote. If the item does not match the computer data, an error message is displayed and a voice message is relayed to the operator to choose the correct item. The scan code is based on the NDC number. The computer will not allow an invoice to be printed and closed until the

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error has been corrected. A person validates constantly while the picker is working. Orders are packed in a brown bag while in the cage but the box is not sealed until sent down the line to be boxed with non-controlled items. The shipping section closes all totes with a piece of PUBLIX security tape. Once the order is completed outside the cage the invoice is generated (computer invoice printed for the box). PUBLIX loads the totes containing controlled substances onto a short conveyor belt outside the controlled substances cage and have the totes travel to the loading bays via the motorized conveyor belt system, stopping for verification in the distribution area. The conveyor belt is approximately 15 ft long and is within sight of all operators. The single individual working in this area will not open any totes, but verify the label and order information on the outside of the tote against a printout. The totes are sent to the shipping department where they are sorted by route and funneled to the appropriate truck for delivery. Controlled substances totes never sit on the loading bay. Every loading bay has cameras looking into the truck as it is loaded. The firm has a full time security staff viewing the cameras at all times. This information is digitally recorded and maintained for 60 days. When the semi trailers are not being actively loaded and manned the security door will be closed and locked. The firm uses a common carrier called Courier Express and UPS. The Courier Express Company was chosen based on services provided. The company was checked for experience and the contract was reviewed by PUBLIX warehouse attorneys. When goods are delivered, all loaded boxes will have the pharmacy designated on the box. A pharmacy associate must sign for the controlled substances. PUBLIX has made all carriers aware that all shipments should be delivered directly to the pharmacy. The driver obtains a signed freight log and delivery log from pharmacy personnel. UPS also schedules pickups from the facility.

b. Controlled Substances Receiving: All deliveries are scheduled ahead of time. The appointment times are logged into the computer system and can be viewed up to one week in advance. Delivery drivers check in at the guard shack upon arrival and security signs the individual in and issue a temporary badge. The driver proceeds to the parking area and presents the ID to the security officer. The security officer verifies the purchase order and calls a receiving associate. There is an assigned

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receiving door where the carrier is sent once verification is completed. The receiving associate checks the purchase order and escorts the driver at all times. When the controlled substance is received, one of the individuals with access to the controlled substances cage is notified. PUBLIX has assigned a receiving center operator to log controlled substances purchase order information into the computer system. The computer system lists the controlled substances based on NDC number. All damaged items discovered are placed in the quarantine cage pending final disposition. All received goods that are not palletized are placed in a rolling cage and transported to the control substances cage area. All palletized items are escorted to the cage immediately after processing by the receiving associate. Once the order is verified, the invoice is stamped with the actual date received. All controlled substances are listed on a separate purchase order. The firm conducts daily cycle counts of all items which had a sale or delivery on that date to verify receipt and distribution information.

c. Samples: The firm does not distribute or receive samples of controlled substances.

d. Verification of DEA Numbers: In spite of the fact that PUBLIX ships only to company owned stores, the firm's computer system verifies each customer's DEA registration prior to filling and processing an order. The firm's computer system will not generate an invoice if the DEA registration has expired. There is a copy of the DEA registration in every store. If the number is expired, no goods will be shipped to the stores. The DEA number and expiration date are printed on each shipping invoice.

e. Loss or Theft: The firm is aware of the requirement to report any theft or loss of a controlled substance to DEA within 24 hours and to follow-up with a full report of the missing items via DEA's Theft or Loss system.

f. Due Diligence/Suspicious Orders: Mr. BAMBERGER understood that the firm is responsible to report suspicious orders of controlled substances to the local DEA office. The firm's computer system sends an alert when established thresholds have been exceeded. The firm has software

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installed which generates orders and is programmed to establish a maximum order quantity based on a store's order history. If a suspicious order is received it is flagged by the computer system and sent to a manager for review. The manager contacts the store to ascertain the reason for the order and either approves or denies the order.

g. Internal Auditing: ARCOS reportable items are reconciled monthly. The firm conducts daily cycle counts based on product sales and receipts. All items with receipts or distributions from the previous day are counted and reconciled prior to shipping or processing for the day. Quarterly audits are conducted by the audit department. The audit department is located at the corporate office in Lakeland, Florida.

h. Suppliers: The firm has no foreign suppliers or customers.

I. Intelligence Information

Nothing to Report

J. Foreign Suppliers and Customers

Nothing to Report

K. Discrepancies and Discussion with Management

On 08-03-2011, DIs James Graumlich and Linda Stocum met with Jason BAMBERGER and Laura SLONE to discuss the results of the inspection. There were no violations discovered during the inspection, but the DIs did discuss the issue of the erroneous receiving dates provided by the firm's computer system via transaction printouts. Firm management was able to explain and reconcile initial deviations in the audit when they realized that the "line item receiving" process for processing their purchase orders resulted in the computer system assigning an erroneous date received to all items once the purchase order was "closed".

DI Graumlich pointed out that this was not a violation due to the fact that the printout was not the firm's official receiving record and was

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simply used to facilitate the audit. But he did point out that firm management needed to understand the records provided for the audit and be able to account for any discrepancies between their primary and secondary records. He affirmed that their primary receipt record needed to accurately reflect the actual quantity received and the actual date of physical receipt. Mr. BAMBERGER stated he understood.

The firm had not modified its security system, but had re-configured the shelving in its cage, blocking one of the motion detectors. DI Graumlich discussed the relocation and addition of motion detectors to properly cover the area. Mr. BAMBERGER made the requested changes and on 09-29-2011, DI Graumlich tested the modifications and found them to be working properly.

L. Verifications

Between 08-06-2011 and 09-06-2011, DI Graumlich verified sales of audited items to the following pharmacies:

Publix Supermarket #0698; Invoice #050740698, Dated: 02-17-2011

Publix Supermarket #0301; Invoice #052770301, Dated: 05-05-2011

Publix Supermarket #0062; Invoice #053310062, Dated: 05-26-2011

DI Graumlich also verified 6 purchases of audited items from the firm's primary supplier, Mallinckrodt, DEA# RM0270037. He spoke with Eileen Spaulding, Compliance Investigator on 09-06-2011 and verified the distribution of items to PUBLIX under P.O. number 0277329-01. She confirmed the sales in question and stated that PUBLIX was a customer in good standing.

M. Special Assignments

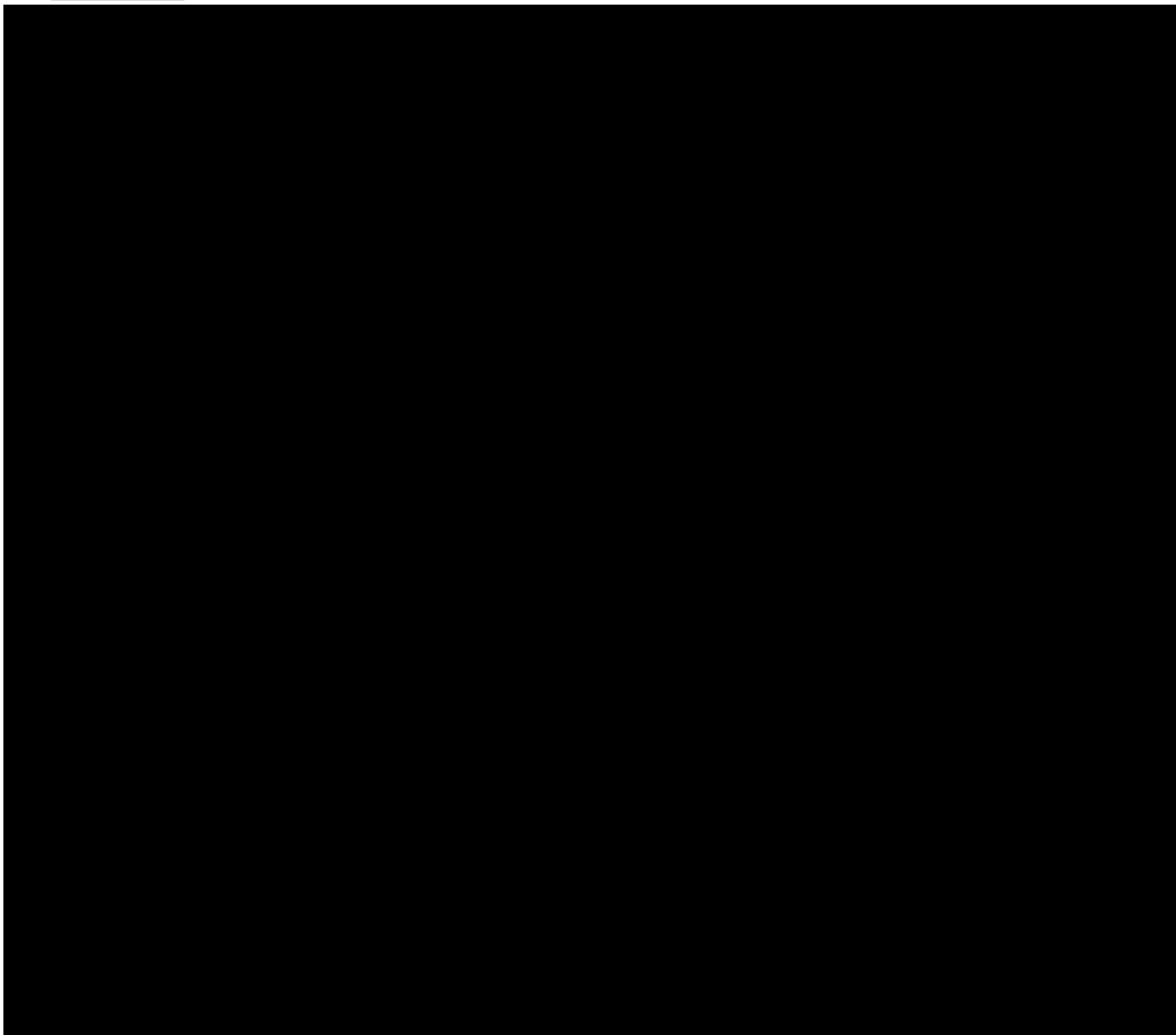
Nothing to Report.

This file is closed.

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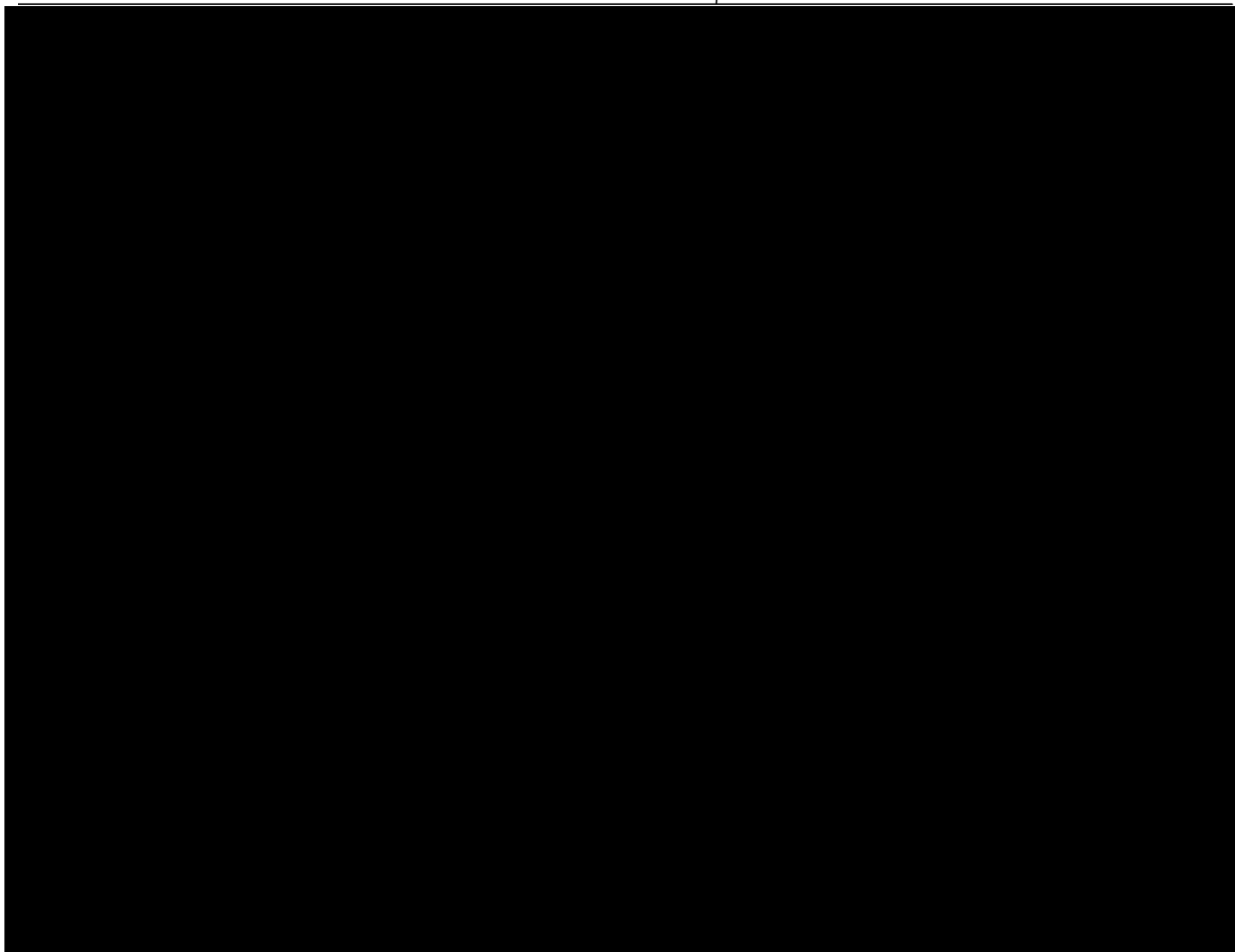
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